

REMARKS

Request for a 1-month Extension of Time for Response

Applicants hereby request a one-month Extension of Time for responding to the outstanding office action with the fee being concurrently paid online with the filing of this response.

Request for Reconsideration

Applicants have carefully considered the matters raised by the Examiner in the Office Communications but remain of the opinion that patentable subject matter is present. Applicants respectfully request reconsideration of the Examiner's position based on the amended claims and the following remarks.

Claim Status and Amendments

Claims 28-32, 34-38, 40-41, 44, 47, 49, 52 and 54-57 are now pending and under consideration. Claims 36, 44 and 54 have been indicated as being allowable.

Claims 28-30, 34-35, 37-38, 40-41, 44, 47, 49, 52 and 55 have been amended, without prejudice to the subject matter of these claims previous to amendment. Claims 50 and 51 have been newly canceled, without prejudice. New claims 56 and 57 are added to more clearly set forth the subject matter of cancelled claims 50 and 51.

As discussed in the following sections, most of the amendments are made to clarify the questions raised by the Examiner in the Office Action and in the telephone interview of December 27, 2007 (see below). Other amendments set forth that which Applicant's consider to be their invention with more particularity and clarity. In addition, the term, "gene[s]" is replaced with "gene(s)" to avoid any confusion wherein a single

set of brackets might be thought to signal a deletion, to conform with conventional U.S. usage indicating the alternative of a singular/plural. Hence, all the amendments are submitted to have their respective support in the previously presented claim set and/or in the application as filed.

Telephone Interview

Applicants' undersigned attorney expresses appreciation for the telephone interview provided by the Examiner on December 27, 2007. During that interview, the Examiner indicated that the transitional phrase "having" (e.g., in claim 28) resulted in the scope rejections. It is submitted that the scope issues have been obviated in view of the current amendments, and that the art rejections are also now addressed.

Claim Rejections - 35 USC §112, First Paragraph

At item 4 of the Office Action, claims 28-31, 34, 35, 37, 38, 40, 41, 47, 49-51, and 55 are rejected under 35 U.S.C. 112, first paragraph, on the grounds that the specification does not enable the artisan, "to make and use the invention commensurate in scope with these claims." In the text bridging pages 2-3 of the Office Action, the Examiner does concede that the specification is,

enabling for nucleic acid probes consisting of SEQ ID NOS 1 and 2 and the complements thereof, as well as probes or primers consisting of 24 consecutive nucleotides of SEQ ID NO: 1 or 2 or the complements thereof, a probe consisting of 21 consecutive nucleotides of SEQ ID NO: 2 that includes the GAG codon at positions 40 to 42 (or the complement of such a probe), a probe consisting of nucleotides 31-51 of SEQ ID NO: 2 (or the complement thereof), and for probes/primers including the previously referenced sequences that have the functional property of specifically hybridizing to and specifically detecting mycobacteria belonging to the *M. tuberculosis* complex . . .

Applicants respectfully disagree with this ground of rejection. Claim 28, as amended to recite, "consisting of a nucleotide sequence selected from the group consisting of . . ." is submitted to be fully enabled by the specification, as conceded by the Examiner. The same reasoning applies to claims 29-31, 34, 35, 37, 38, 40, 41, 47, 49-51, and 55.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

Claim Rejections - 35 USC §112, Second Paragraph

At item 6 of the Office Action, the Examiner has rejected claims 47, 49-52, and 55 as allegedly indefinite under 35 U.S.C. 112, second paragraph.

The Examiner has alleged that the term, "step" lacks antecedent basis in claims 47 and 49-51. The Examiners attention to this point is appreciated, and the claims are now amended to provide a clear basis for the term "step" or "steps."

In addition, the Examiner has alleged that claims 50-51 are indefinite for describing how the method will differentiate an infection by BCG from an infection by a virulent mycobacterium of M. tuberculosis complex. Claims 50-51 are now cancelled, thus obviating this ground of rejection. New claims 56 and 57 are submitted to be clear and definite.

The Examiner has also alleged that claim 52 lacks a clear basis for the term "step," for "measuring a length of" in relation to "identifying," and for reciting upstream and downstream positions. Amended claim 52 obviates this ground of rejection by reciting "the steps of" after "comprising" and by simplifying the description of step (1) to remove unnecessary elements, and by adding the following phrase to step (2):

wherein said length of the amplification products enables determining the group to which said strains of *M. tuberculosis* complex belong.

The Examiner has alleged that claim 55 is indefinite due to a lack of antecedent basis for "steps" and "said nucleotide sequence of mycobacteria strains of *M. Tuberculosis* complex." Claim 55 has been amended as suggested by the Examiner, thus obviating this ground of rejection.

For all of these reasons, reconsideration and withdrawal of the rejection under 35 USC § 112, second paragraph, is respectfully requested.

Claim Rejections - 35 USC § 102(b)

At item 8 of the Office Action, the Examiner has rejected claim 37 is rejected under 35 U.S.C. 102(b) as allegedly anticipated by Blakely et al. (US 5,418,162). The Examiner takes the position that claim 37, "broadly encompasses any 21 mer probe 'having a sequence' of 'a region., . .comprising the GAG codon;' i.e., any 21 mer."

Applicants respectfully disagree. Claim 37, as amended, particularly recites, a "probe consisting of 21 consecutive nucleotides of a region of SEQ ID No: 2 comprising the GAG codon in positions 40-42 or the complement of said region," thus obviating this ground of rejection. It is submitted that Blakely does not teach or suggest the particular probe defined by claim 37.

At item 9 of the Office Action, claim 38 is rejected under 35 USC 102(b), as allegedly anticipated by Brennan et al. (US 5,474,796). The Examiner takes the position that, "Brennan discloses an array of oligonucleotides comprising all possible 10-mers (see entire reference, particularly Example 4). Each of

the probes of Brennan may be 'composed of' the nucleotide present in positions 31 to 51 of SEQ ID No: 2."

Applicants respectfully disagree. Claim 38, as amended, no longer recites the terms, "comprising" and "composed", thus obviating this ground of rejection. It is submitted that nowhere does the Brennan reference teach or suggest the specific probes as defined by claim 38:

A nucleotide probe consisting of a nucleotide sequence which consists of nucleotides in positions 31 to 51 of SEQ ID No: 2 or the complement of said sequence.

For all of these reasons, reconsideration and withdrawal of all of the rejections under 35 USC 102(b) is respectfully requested.

Conclusion

In view of the foregoing, it is respectfully submitted that the Application is in condition for allowance, and this action is respectfully requested.

Should any extensions of time or fees be necessary in order to maintain this Application in pending condition, appropriate requests are hereby made and authorization is given to debit account # 02-2275.

Respectfully submitted,

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